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09/211,507	12/14/1998	ALAN R. HIRSCH	054012-0009	9827

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WHYTE HIRSCHBOECK DUDEK S C
111 EAST WISCONSIN AVENUE
SUITE 2100
MILWAUKEE, WI 53202

EXAMINER

TATE, CHRISTOPHER ROBIN

ART UNIT PAPER NUMBER

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BEFORE THE BOARD OF PATENT APPEALS

AND INTERFERENCES

Date mailed
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Paper No. 31

Application Number: 09/211,507
Filing Date: 14 December 1998
Appellant(s): Hirsch

Kristine M. Strodhoff

For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed November 25, 2002.

Art Unit: 1651

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

Appellant's brief includes a statement that claims stand together (see page 3 of Appellant's Brief).

(8) *Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

Art Unit: 1651

(9) *Prior Art of Record*

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

Doty et al. "The Smell Identification TestTM Administrative Manual",
Philadelphia Sensorics, Inc. (1983), 22 pages.

(10) *Grounds of Rejection*

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1, 2, 4-6, 9-11, 35, and 39-44 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of increasing and/or decreasing blood flow to the vagina via inhaling the particular commercial odorants (see, e.g., page 12, lines 1-13 of the instant specification) and/or mixtures thereof instantly demonstrated, does not reasonably provide enablement for a method of increasing and/or decreasing blood flow to the vagina via inhaling any undefined odorant therein and/or the subjective odorants instantly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Based upon Applicant's response and Declaration of July 6, 2001, it is deemed that Applicant has reasonably demonstrated that the particular commercial odorants (see, e.g., page 12, lines 1-13 of the instant specification) act to alter blood flow to the vagina via inhaling an effective amount thereof. However, the claims encompass such unusual use via inhaling any undefined odorant and/or the subjective odorants instantly claimed which is clearly beyond the

Art Unit: 1651

scope of the instantly disclosed invention. The instantly claimed odorants are highly subjective with respect to the actual odors being encompassed and, thus, are not enabled - e.g., based upon the ingredients within a given recipe of pumpkin pie or banana nut bread, numerous distinct odors particular to that given recipe would be emitted therefrom. This is also the case for baby powder, which is actually talc to which a particular perfume is added and which varies by commercial manufacturer; and is also the case for cucumber (e.g., based upon the brand, species, age/ripeness, geographic location in which it is grown, etc.), licorice-based odorants (e.g., Good and Plenty® candy has a distinct odor from that of some other licorice based products such as anise), and chocolate odorant (e.g., milk chocolate has a distinct odor from dark chocolate). In addition, it is noted in several instances that using the same odorant or mixture of odorants that cause an increased blood flow to the vagina to some females also cause a decrease in blood flow to the vagina in other females. Further, as disclosed by Doty (Philadelphia Sensorics, 1983), there are numerous variables such as an individual's occupation, general health, psychological state, and age which play a role in assessing sensory function of smell (see, e.g., pages 16-18). Therefore, altering blood flow to the vagina via the inhalation of such odorants, including the undefined and/or broadly defined odorants instantly claimed, as well as any undefined amounts thereof, is considered to be highly unpredictable between females based upon such variables.

Accordingly, it would take undue experimentation without a reasonable expectation of success for one of skill in the art to make and/or use an odorant having the unusual disclosed/claimed functional effect, other than inhaling one of the particular demonstrated

Art Unit: 1651

commercial odorants or mixtures thereof, in an amount effective to provide the claimed alteration in blood flow to the vagina.

Claims 1, 2, 4-6, 9-11, 35, and 39-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons set forth in the previous Office action which are restated below.

The metes and bounds of the undefined or subjective odorants recited in claims 1, 2, 4-6, 9-11, 35, and 39-44 are not clearly nor adequately delineated making the claims unclear. For example, based upon the ingredients within a given recipe of pumpkin pie or banana nut bread, numerous distinct odors particular to that given recipe would be emitted therefrom. This is also the case for baby powder, which is actually talc to which a particular perfume is added and which varies by commercial manufacturer; and is also the case for cucumber (e.g., based upon the brand, species, age/ripeness, geographic location in which it is grown, etc.), licorice-based odorants (e.g., Good and PlentyTM has a distinct odor from that of some other licorice based products such as anise or other products having licorice as a base in combination with other ingredients), chocolate odorant (e.g., milk chocolate has a distinct odor from dark chocolate). The subjective nature of the recited odorants (any of which is deemed essential in terms of adequately defining these particular active ingredients within the claimed *in vivo* method of altering blood flow to the vagina) causes these claims to be very ambiguous and unclear.

Art Unit: 1651

(11) Response to Argument

Appellant argues that the Examiner has provided no good basis for his position regarding the U.S.C. 112, first and second paragraph rejections above with respect to the scope of enablement rejection (112, first paragraph) and the metes and bounds of the claimed mixture of subjective odorants not being clearly nor adequately delineated (112, second paragraph).

Appellant argues that, first of all, the Examiner erroneously contends that the claims encompass "any undefined odorant and/or the various mixtures of subjective odorants" instantly claimed, and that the pending claims are directed to an article comprising specified mixtures of odorants. Appellant also argues that the Examiner merely asserts that the instantly claimed odorants are highly subjective with respect to the actual odors being encompassed, stating that a given recipe of pumpkin pie or banana nut bread varies according to the ingredients, baby powder varies by commercial manufacturer, cucumber varies based upon the brand, species, age/ripeness, geographic location in which it is grown, etc., licorice-based odorants such as Good and Plenty™ (as disclosed in the instant specification) has a distinct odor from that of some other licorice based products such as anise - including the fact that Good and Plenty® candy is composed of a mixture of ingredients other than anise), and chocolate such as milk chocolate has a distinct odor from dark chocolate. However, as discussed in the above rejections, other than using the particular demonstrated commercial odorants (or mixtures thereof) to provide the unusual recited functional effect within the instantly claimed *in vivo* method (i.e., increasing or decreasing blood flow to the vagina via inhalation), the metes and bounds of the various subjective odorants (within the various recited mixtures thereof) are not clearly nor adequately delineated in terms of what odorants are actually being encompassed by such subjective odorant

Art Unit: 1651

terms within the claimed *in vivo* method - e.g., "licorice-based odorant", "banana nut bread", "pumpkin pie odorant", "baby powder odorant", and "chocolate odorant", much less mixtures thereof. Thus, this is not merely an assertion by the Examiner because such odors are, in fact, highly subjective for these very reasons (as discussed above). How can they not be? It is further noted that, as drafted, the instantly claimed mixtures of such odorants do not even define the amounts and/or ratios of one odorant to the other - i.e., as drafted, the instant claims encompass the *in vivo* use of a mixture of any and all percentages and/or ratios of one recited odorant to the other. For example, one mixture of odorants could contain 99.99% of a first odorant and 0.01% of a second odorant, or alternatively contain 0.01% of the first odorant and 99.9% of the second odorant. This would have a dramatic impact upon the claimed *in vivo* method with respect to the overall odor emitted from such an odorant mixture, as well as the functional effect(s) provided by each odorant mixture upon *in vivo* administration, including in terms of determining the actual odorant encompassed by any one of the various mixtures of odorants instantly claimed.

Appellant further argues that the Examiner asserts that the use of other odorants would be highly unpredictable between females and should be limited to the commercially identified odorants instantly disclosed (see, e.g., page 12, lines 1-13 of the instant specification) because the same mixture of odorants can cause an increased blood flow to the vagina in some females and a decreased blood flow in the vagina of other females. However, this argument by itself, shows the highly unpredictable nature of such odorants and odorant mixtures upon a given female. Also, the nature of the claimed/disclosed invention can be considered to be a female ViagraTM (i.e., those odorants which are disclosed as causing an increase in blood flow to the vagina) since

Art Unit: 1651

Viagra™ is used to increase blood flow to the penis of a male and there have been countless unsuccessful attempts over the centuries to devise various types of female sexual arousal formulations.

In addition, Appellant argues that the Examiner cites Doty et al. without any basis for support to show that variables such as occupation, general health, psychological state and age, make the use of other odorants highly unpredictable between females. However, although the Doty et al. reference is mainly directed to tests for identifying odorants, the overall teachings of Doty et al. show that, in general, these variables play a role in the ability of a person to perceive a given odor (and also that women and men perceive odors differently with regard to intensity, pleasantness, coolness/warmth, irritation, and familiarity - see, e.g., page 4 of Doty et al). Accordingly, it would not be reasonable for one of skill in the art to wholly dissociate such variables in the smell perception of an odor from the physiological effect(s) the perceived odor has upon an individual, including a female individual.

Appellant also argues that known methods in the art can be readily used for identifying and/or preparing odorants with the scope of the claims and that those of ordinary skill in the art of odor science would readily utilize such known and used instruments to do so. However, this type of identify-and-test or make-and-test reasoning does not obviate the above U.S.C. 112 first and second paragraph rejections for the reasons of record including that the metes and bounds of the instantly recited highly subjective odorant terms within the claimed odorant mixtures do not clearly nor adequately define these essential ingredients nor are these broad, highly subjective odorant terms within the scope of the instantly demonstrated invention, which utilized particular

Art Unit: 1651

commercial odorants, and mixtures thereof, to show the unusual *in vivo* effect instantly claimed (i.e, increasing and/or decreasing blood flow to the vagina of female volunteers).

In addition, Appellant argues that other issued patents (some by the Appellant) claim various odorants for various methods of treatment. However, this argument is not deemed persuasive for two reasons. Firstly, the merits of the instant application, including the Office actions of record, stand on their own. Secondly, this argument is not relevant to the instant teachings with respect to odorants having the unusual functional effects upon females as instantly disclosed/claimed.

Art Unit: 1651

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,



Christopher Tate
December 17, 2002

Conferees



Michael G. Wityshyn
Supervisory Patent Examiner
Technology Center 1600

Kristine M. Strodhoff
Whyte Hirschboeck Dudek S.C.
111 East Wisconsin Avenue, Suite 2100
Milwaukee, Wisconsin 53202


CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600